IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
(BALTIMORE DIVISION)

DIANA HANSON *
654 211 Street
Pasadena, Maryland 21122 *

and *

JAMES HANSON *
654 211 Street
Pasadena, Maryland 21122 *

Plaintiffs * Case No.: 1:21-CV-01807

v. *

AZIYO BIOLOGICS, INC. *
251 Little Falls Drive
Wilmington, DE 19808 *

and *

MEDTRONIC, PLC *
251 Little Falls Drive
Wilmington, DE 19808 *

and *

MEDTRONIC USA, INC. *
251 Little Falls Drive
Wilmington, DE 19808 *

and *

MEDTRONIC, INC. *
251 Little Falls Drive
Wilmington, DE 19808 *

Defendant. *

* * * * * * * * * * * * *

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs, by and through their attorneys, Roy L. Mason, Zachary E. Howerton, and the law offices of Smouse & Mason, LLC, hereby sue Defendant, and for cause state:

INTRODUCTION

1. This action seeks to recover damages for the personal injuries suffered by DIANA HANSON, which were the direct and proximate result of the wrongful conduct of AZIYO BIOLOGICS, INC., MEDTRONIC, PLC, MEDTRONIC USA, INC., and MEDTRONIC, INC. in connections with the research, testing, design, development, manufacture, production, inspection, labeling, advertisement, marketing, promotion, sale, and distribution of FiberCel Fiber Viable Bone Matrix ("FiberCel").

PARTIES, JURISDICTION, AND VENUE

2. Plaintiff DIANA HANSON ("Plaintiff") is and at all relevant times was a resident of the State of Maryland, residing in Anne Arundel County, Maryland.

3. Plaintiff JAMES HANSON ("Plaintiff") is and at all relevant times was a resident of the State of Maryland, residing in Anne Arundel County, Maryland and is married to Plaintiff Diana Hanson..

4. Defendant AZIYO BIOLOGICS, INC. ("Aziyo") is a Delaware corporation, whose registered agent for services of process is Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808. Aziyo's principal place of business is located at 12510 Prosperity Drive, Suite 370, Silver Springs, Maryland 20904.

5. Aziyo sells a variety of medical products, including implantable electronic devices, orthopedic and spinal repair products, and soft tissue reconstruction products.

6. Upon information and belief, Aziyo developed, manufactured, marketed, promoted, distributed, supplied and/or sold FiberCel, which was implanted into Plaintiff and which is the subject of this complaint.

7. Defendant MEDTRONIC, PLC, is incorporated in Ireland, having its principal place of business at 20 Lower Hatch Street, Dublin, 2, Ireland. MEDTRONIC, PLC's U.S. operational headquarters are located at 710 Medtronic Parkway, Minneapolis, MN 55432-5604 USA with a registered agent for service located at Corporation Service Company, 251 Little Falls Drive, Wilmington Delaware 19808. MEDTRONIC, PLC is the parent company of MEDTRONIC, INC. MEDTRONIC, PLC does business throughout the United States.

8. Defendant MEDTRONIC, USA, INC is incorporated in Minnesota, having its principal place of business at 710 Medtronic Parkway, Minneapolis, MN 55432-5604 USA with a registered agent for service located at Corporation Service Company, 251 Little Falls Drive, Wilmington Delaware 19808. MEDTRONIC, USA, INC does business throughout the United States.

9. Defendant MEDTRONIC, INC is incorporated in Minnesota, having its principal place of business at 710 Medtronic Parkway, Minneapolis, MN 55432-5604 USA with a registered agent for service located at Corporation Service Company, 251 Little Falls Drive, Wilmington Delaware 19808. MEDTRONIC, INC does business throughout the United States.

10. MEDTRONIC, PLC, MEDTRONIC, USA, INC, and MEDTRONIC, INC (collectively, "Medtronic") develop therapeutic and diagnostic medical products, and is among the world's largest medical technology, services, and solutions companies.

11. Upon information and belief, Medtronic was designated as the exclusive U.S. distributor of the FiberCel manufactured by Defendant Aziyo.

12. At all times relevant, Medtronic distributed, supplied, and/or sold FiberCel in Maryland which was implanted into Plaintiff and which is the subject of this complaint.

13. Defendants, at all times relevant to this lawsuit, manufactured, developed, designed, marketed, distributed, promoted, supplied, and/or otherwise sold (directly or indirectly) FiberCel to various locations for use in surgeries requiring bone grafting, including to Anne Arundel Medical Center in Maryland where it was surgically implanted into Plaintiff Diana Hanson, causing her to suffer harm as described herein.

14. This claim arises out of a cervical spine operation performed on Plaintiff Diana Hanson at Anne Arundel Medical Center in Anne Arundel County, Maryland on March 24, 2021, in which FiberCel was surgically implanted into her body.

15. This is an action seeking damages in excess of $75,000.00, exclusive of interest, costs and attorney's fees.

16. Federal subject matter jurisdiction arises out of diversity of citizenship pursuant to 28 U.S.C. § 1332, as this is a civil action where the matter in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs, and is between citizens of different states. In addition, 28 U.S.C. § 1367 provides supplemental jurisdiction for the state law claims.

17. Further, this Court has personal jurisdiction over Defendants because Aziyo and Medtronic conduct business in Maryland, purposefully direct or directed their actions toward Maryland, and because they have the requisite minimum contacts with Maryland to permit the Court to exercise jurisdiction.

18. Venue in this District is proper under 28 U.S.C. § 1391(b) because the events giving rise to the action occurred in Anne Arundel County, located entirely within the geographic boundaries for the District of Maryland.

FACTS COMMON TO ALL COUNTS

19. FiberCel Fiber Viable Bone Matrix ("FiberCel") is made from human tissue consisting of cancellous bone particles with preserved cells, combined with demineralized cortical fiber. It is engineered to be like natural tissue and is used as a bone void filler in various orthopedic and spinal procedures. The allografts contain the scaffold, growth factors and cells required for regeneration critical for successful bone formation.

20. FiberCel is marketed for use in orthopedic and reconstructive bone grafting procedures with the use of autologous bone or other forms of allograft bone or alone as a bone graft. FiberCel is made with donor tissue and growth factor cells.

21. On June 20, 2019, Aziyo announced it had signed an exclusive, multi-year distribution agreement with defendant Medtronic in the U.S. orthopedic market. According to the agreement, Aziyo agreed to manufacture and supply FiberCel to Medtronic for distribution through the company's sales and marketing organization.

22. On June 2, 2021, the United States Food & Drug Administration (FDA) issued an urgent voluntary recall of FiberCel, specifically three products from Donor Lot Number NMDS210011: VMB9901, VBM9905, and VBM9910.

23. Aziyo initiated the voluntary recall in response to reports of patients testing positive for Tuberculosis and post-surgical infections following the surgical implantation of FiberCel as part of an orthopedic or spinal procedure.

24. Tuberculosis ("TB") is an infectious disease caused by bacteria known as Mycobacterium tuberculosis. TB is highly contagious, and mostly impacts the lungs, but can also spread through the lymph nodes to other parts of the body, including the kidneys, brain, and spine.

25. Once mycobacterium tuberculosis is introduced to the body, the bacteria must then proliferate within the new host for the host to develop disease. When this bacteria is introduced in a surgical wound, the patient is already in an immunocompromised position, causing them to have an increased likelihood of developing TB, which can be fatal.

26. The recall contaminated FiberCel lot contained 154 units delivered to 20 states. The recall involves a total of 113 patients, the vast majority of whom are receiving treatment for tuberculosis. Eight patients have died after their procedures, although the cause of death is still unknown. The Centers for Disease Control and Prevention have identified at least 72 patients who have exhibited clinical or diagnostic findings consistent with tuberculosis infection. 18 units were sequestered by states to prevent further use in surgeries. Aziyo has stated that, "[returned] samples of the recalled product tested positive for Mycobacterium tuberculosis in PCR analysis by a lab contracted by the CDC."

27. Upon information and belief, Anne Arundel Medical Center received multiple contaminated units from FiberCel Donor Lot No. NMDS210011, and the contaminated units were implanted into multiple patients, including Plaintiff.

28. Defendant Aziyo has acknowledged that at least one hospital reported post-surgical infections in seven of twenty-three patients that received FiberCel from Donor Lot No. NMDS210011. At least four patients that have received FiberCel from this Donor Lot have tested positive for Tuberculosis.

29. This recall acknowledged that viruses and bacteria, including Tuberculosis, can be transplanted into patients along with the FiberCel product.

30. Plaintiff Diana Hanson underwent a cervical spine surgery on March 24, 2021 at Anne Arundel Medical Center in Maryland.

31. Plaintiff Diana Hanson's surgery included bone grafting, utilizing FiberCel from Donor Lot Number NMDS210011.

32. Unbeknownst to Plaintiff or her physicians at the time of her surgery, the FiberCel implanted into Plaintiff was contaminated with tuberculosis.

33. Following the procedure, the surgical wound became infected and required two additional procedures to clean the wound and enhance healing. The wound cultures did not grow any identifiable bacteria.

34. On June 6, 2021, Diana received a call from Dr. Chad Patton, MD informing his patient that the Hospital had received notice of the FiberCel recall and that contaminated product had been used in Diana's surgery.

35. This call was followed by a letter on June 10, 2021 from Luminis Health and the Chief Medical Officer notifying Diana that the Hospital was working with the Maryland Department of Health and the Centers for Disease Control and Prevention (CDC) to determine the best treatment options and that both agencies would be involved in developing a treatment plan for her.

36. Diana had blood work that tested positive for the TB antibodies. She had been exposed to TB. The chest X-Rays remained clear.

37. The Plaintiff is continuing to be treated as though she has active tuberculosis and taking four prescribed medications, 12 pills every day, to actively manage her condition. Diana

has experienced the significant side effects of nausea, vomiting, and headache which accompany this medication.

38. Plaintiff also requires constant monitoring of her liver function as the TB medication can cause liver toxicity. This requires routine bloodwork to monitor the liver function and her postoperative response to the mediation.

39. Plaintiff is experiencing significant neck pain requiring pain medication. The surgeon has told her that he is uncertain what the cause of the pain may be as they have not had to address this type of contamination before and so they are "flying blind" in deciding how to address the situation.

40. Diana will require revision surgery to remove the contaminated FiberCel product and to insert a new bone matrix free from contamination.

41. Plaintiff's revision surgery will subject her to much greater risks of complication than she had before the initial surgery.

42. Plaintiff's diagnosis of potential tuberculosis will continue to require extensive and invasive medical protocols to monitor her clinical status and manage the manifestation of this disease.

43. Plaintiff would not have suffered from tuberculosis, as well as the need to multiple undergo subsequent revision surgeries, had Defendants sold and distributed a product that was free from tuberculosis contamination.

44. Plaintiff will require continued medical monitoring now and into the future in order to address Plaintiff's health related to the ongoing and serious nature of her tuberculosis diagnosis.

45. The Department of Health has requested ongoing monitoring of Diana's husband and children, a 4-year-old and a 6-year-old, for signs and symptoms of tuberculosis

46. Diana's family has been counselled to decrease interaction with friends and family causing increasing isolation of the client and family.

47. Plaintiff is an active schoolteacher in the Anne Arundel School System. She has used up all of her vacation time to deal with these medical problems, ultimately being forced to take unpaid leave. It is uncertain if Diana will be permitted to return to her classroom in the Fall causing further financial and emotional stress.

48. Plaintiff would not have suffered these issues, had Defendants sold and distributed a product that was free from tuberculosis contamination.

49. As a direct and proximate result of Plaintiff's exposure to Defendants' contaminated FiberCel product used in her cervical spine surgery, Plaintiff has suffered and continues to suffer from severe pain and discomfort, emotional distress, the loss of daily functions, and economic loss, including, but not limited to, present and future medical expenses, lost earnings, and future lost earning capacity, all of which are a direct result of Defendants' liability producing conduct.

CAUSES OF ACTION

FIRST CAUSE OF ACTION: NEGLIGENCE

50. Plaintiff incorporates the foregoing paragraphs as though the same were set forth at length herein.

51. Defendants owed a duty to Diana Hanson to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality, assurance, quality control, and distribution of FiberCel into the stream of commerce,

including a duty to assure that the FiberCel would not cause those who used it, including Diana Hanson, to suffer adverse harmful effects.

52. Defendants failed to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control and distribution of FiberCel.

53. Defendants knew or should have known that those individuals who used the defective FiberCel were at risk for suffering harmful effects from it, including but not limited to, tuberculosis, as well as other severe injuries which are permanent and lasting nature, physical pain, mental anguish, and diminished enjoyment of life.

54. Defendants were negligent in designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing, and sale of FiberCel. The negligence of Defendants, their agents, servants, and employees, included, but was not limited to, the following acts and/or omissions:

a. Designing, manufacturing, producing, creating, and/or promoting FiberCel without adequately, sufficiently, or thoroughly testing the FiberCel units to ensure they were free from contamination of communicable diseases, including but not limited to, tuberculosis;

b. Not conducting a sufficient quality control testing program to determine whether or not the subject FiberCel was manufactured properly and was free from contamination or other defects making it unsafe for users of the product;

c. Failing to adequately and properly obtain and review complete donor medical history;

d. Negligently failing to timely recall their dangerous and defective FiberCel lots at the earliest date that it became known that certain lots of FiberCel were, in fact, dangerous and defective;

e. Negligently manufacturing FiberCel in a manner that was dangerous to those individuals who had FiberCel transplanted into their bodies;

f. Negligently producing FiberCel in a manner that was dangerous to those individuals who had it transplanted into their bodies;

g. Failing to warn individuals who were using the product of the risks of contracting tuberculosis; and

h. Were otherwise careless and negligent.

55. Defendants knew or should have known that consumers, such as Plaintiff Diana Hanson, would suffer foreseeable injury and be at increased risk of suffering an injury as a result of Defendants' failure to exercise ordinary care, as set forth above.

56. Defendants' negligence was the proximate cause of Diana Hanson's physical, mental, emotional injuries and harm, and economic loss.

57. By reason of the foregoing, Defendants are liable to Diana Hanson for all of her injuries, harm, damages, and economic and non-economic losses in an amount to be determined in the future.

SECOND CAUSE OF ACTION: BREACH OF IMPLIED WARRANTY

58. Plaintiff incorporates the foregoing paragraphs as though the same were set forth at length herein.

59. Defendants are in the business of designing, manufacturing, supplying, selling, and placing into the stream of commerce certain goods, including FiberCel.

60. By placing FiberCel into the stream of commerce, Defendants impliedly warranted that it was merchantable and fit and safe for its intended use.

61. The FiberCel placed into the stream of commerce by the Defendants and implanted into Plaintiff was contaminated, leading those persons who received FiberCel implants to develop tuberculosis, including Plaintiff, and accordingly, was not fit, safe, or merchantable for its intended use.

62. The contamination in the FiberCel, manufactured, supplied, and placed into the stream of commerce by Defendants was present at the time the FiberCel units left Defendants' control and at the time it was implanted into Plaintiff as part of her spinal operation.

63. Defendants breached the implied warranty for FiberCel because it was contaminated, unmerchantable, and not fit for its intended purpose, resulting in personal injuries suffered by Plaintiff Diana Hanson, including her development of tuberculosis.

64. Plaintiff Diana Hanson was a foreseeable user of the FiberCel designed, manufactured, and placed into the stream of commerce by Defendants.

65. By reason of the foregoing, Defendants are liable to Plaintiff Diana Hanson for her injuries, harm, damages, and economic and non-economic losses in an amount to be determined at trial.

THIRD CAUSE OF ACTION: BREACH OF EXPRESS WARRANTY

66. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if they were set forth at length herein.

67. At all times mentioned, Defendants expressly represented and warranted to Plaintiff and Plaintiff's agents and physicians, by and through statements made by Defendants and their authorized agents or sales representatives, orally and in publications, packages inserts, and

other written materials intended for physicians, medical patients, and the public, that FiberCel is safe, effective, fit, and proper for its intended use. Plaintiff and Plaintiff's physicians utilized FiberCel relying upon these warranties.

68. Defendants' own promotion states that FiberCel is processed in sterile conditions and is screened for bacteria and communicable disease.

69. In utilizing FiberCel, Plaintiff relied on the skill, judgement, representation, and foregoing express warranties of the Defendants. These warranties and representations were false in that FiberCel is unsafe and unfit for its intended uses.

70. As a result of the abovementioned breach of express warrantied by Defendants, Plaintiff suffered injuries and damages as alleged herein.

FOURTH CAUSE OF ACTION: MEDICAL MONITORING

71. Plaintiff hereby incorporates by reference the allegations contained in the preceding paragraphs of this Complaint as if they were set forth at length herein.

72. As a result of the Defendants' negligence, Plaintiff has been treated as though she has a diagnosis of TB and may in the future experience ongoing symptoms of TB, in addition to other injuries and harm that she may suffer as a result of her exposure to TB and subsequent need for revision surgery.

73. A monitoring procedure exists to monitor Plaintiff's TB because all TB patients require continual and ongoing monitoring of their potentially deadly disease.

74. Plaintiff will be required to undergo testing and analysis to monitor the presence, spread and/or progression of her TB.

75. Ongoing TB testing requires expenditures of time and money.

76. The prescribed monitoring regime is reasonably necessary according to the CDC and Maryland Health Department.

77. Defendants' acts were both negligent and reckless, and they should be held accountable, and should compensate Plaintiff for the ongoing costs of monitoring her TB status.

WHEREFORE, Plaintiff prays for relief against Defendants, jointly and severally, as follows:

a. Compensatory damages exclusive of interest and costs, and in an amount to fully compensate Plaintiff for all past, present, and future pain and suffering;

b. Special damages, exclusive of interest and costs, and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present;

c. An order to establish a medical monitoring protocol for Plaintiff to monitor her health;

d. Attorneys' fees, expenses, and costs of this action;

e. Pre-judgement and post-judgement interest in the maximum amount allowed by the law; and

f. Such further relief as this Court deems necessary, just, and proper.

Respectfully submitted,

SMOUSE & MASON, LLC

/s/ Roy L. Mason

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Counsel for the Plaintiffs

JURY DEMAND

The Plaintiff herein demands that this matter be heard in front of a jury.

/s/ Roy L. Mason
Roy L. Mason (Bar No. 00922)